

REMARKS

Applicants respectfully request reconsideration of the present application. No new matter has been added to the present application. Claims 2-13 have been rejected in the Office Action. Claims 2-4, 6, and 7-13 have been amended in this Amendment. No additional claims have been canceled and no new claims have been added. Accordingly, claims 2-13 are pending herein. Claims 2-13 are believed to be in condition for allowance and such favorable action is respectfully requested.

Applicants' representative thanks Examiner Natalie Pass and Supervisory Examiner Joseph Thomas for participating in a telephonic interview on May 23, 2006. During the interview, the rejections made under 35 USC §§ 101, 102, 103, and 112, as well as the non-statutory double patenting rejections, were discussed. Examiners indicated that amendments proposed to the independent claims would obviate the 101, 112, and double patenting rejections. In addition, differences between the independent claims and the applied art, U.S. Patent Nos. 4,293,845 to Villa-Real ("Villa-Real") and 5,072,383 to Brimm et al. ("Brimm") were discussed. In particular, for example, Applicants' representative noted the general differences between Villa-Real and the claimed invention, as well as the claimed invention's association of medications with routes, dose amounts, dose forms, and frequencies. Examiners indicated that Applicants' representative's arguments would be kindly considered. With respect to claims 8, 10, and 12, Examiners recommended potential amendments to clarify the associations of medications with routes, and of routes with dose amounts, dose forms, and frequencies, as well as to clarify the interactive nature of the claimed invention, so as to potentially overcome the current 102 and 103 rejections.

Amendments to the Claims

Claims 2-4, 6, and 7-13 have been amended. Care has been exercised to avoid the introduction of new matter.

Support for the amendments can be found in the Specification, for example, at: page 20, lines 11-14 (¶ [0094]); page 21, line 10 through page 22, line 17 (¶¶ [0098]-[0099]); and, page 23, lines 1-11 (¶ [0101]).¹

Double Patenting Rejections

Claims 2-6 were rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,317,719 (“the ‘719 patent”).

Claim 2, as amended herein, is patentably distinct from claim 1 of the ‘719 patent. Claim 2, as amended herein, recites elements, *inter alia*, of: receiving a request to create an electronic medication order for a patient; displaying a list of available medications; determining whether the selected medication is to be expertly dosed; if the medication is to be expertly dosed, then expertly dosing the medication using a knowledge base; and if the medication is not to be expertly dosed, then displaying standard dosage recommendations. Claim 1 of the ‘719 patent does not recite elements of: receiving a request to create an electronic medication order for a patient; displaying a list of available medications; determining whether the selected medication is to be expertly dosed; if the medication is to be expertly dosed, then expertly dosing the medication using a knowledge base; and if the medication is not to be expertly dosed, then displaying standard dosage recommendations. As such, claim 2, as amended herein, is

¹ Page and line numbers correspond to the specification, as filed. Paragraph numbers correspond to the published application (United States Patent Application Pub. No. US 2002/0002473 A1, published on Jan. 3, 2002).

patentably distinct from claim 1 of the '719 patent. Claims 3-6, by virtue of their dependency from claim 2, are also patentably distinct from claims 2-5 of the '719 patent. Applicants respectfully request withdrawal of the obviousness-type double patenting rejections.

Rejections under 35 U.S.C. § 101

Claims 2-13 were rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter. Examiner asserts that no provision in the body of the claims permits the functionality claimed in the preamble to be realized and thus renders the claims incapable of producing a tangible result. Examiner concedes that the claims recite useful and concrete results. *See Office Action*, at page 5.

Independent claims 2, 8, 10, and 12, as amended herein, recite a step in the body of the claims for creating an electronic medication order. As such, claims 2, 8, 10, and 12, as amended herein, are capable of producing a tangible result. Independent claim 7, as amended herein, recites in the body of the claim a storage component for storing an electronic prescription created for a patient. As such, claim 7, as amended herein, is capable of producing a tangible result. As the remaining claims depend from independent claims 2, 7, 8, 10, and 12, the remaining claims are also capable of producing a tangible result, and are thus directed to statutory subject matter. Applicants respectfully request withdrawal of the 101 rejections of claims 2-13 as they are directed to producing a useful, concrete, and tangible result.

Rejections under 35 U.S.C. § 112

Claims 2-13 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. More particularly, Examiner asserts that the body of claims 2-13 do not recite creating steps or components while the preamble of claims 2, 8, 10, and 12 recite a "method for

creating an electronic medication order” and the preamble of claim 7 recites a “system for creating an electronic prescription for a patient.”

Independent claims 2, 8, 10, and 12, as amended herein, recite a step in the body of the claims for creating an electronic medication order. As such, claims 2, 8, 10, and 12, as amended herein, are not indefinite under 35 U.S.C. 112. Independent claim 7, as amended herein, recites in the body of the claim a storage component for storing an electronic prescription created for a patient. As such, claim 7, as amended herein, is not indefinite under 35 U.S.C. 112. Independent claims 2, 7, 8, 10, and 12, as amended herein, and the remaining claims, by virtue of their dependency from the independent claims, are not indefinite under 35 U.S.C. 112, second paragraph. Applicants respectfully request withdrawal of the 112 rejections.

Rejections under 35 U.S.C. § 102

Claims 2, 4, and 6-7 were rejected under 35 U.S.C. 102(b) as being anticipated by Villa-Real. As Villa-Real fails to teach each and every element of claims 2, 4, and 6-7, Applicants respectfully request withdrawal of this rejection.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference.” *Verdeggal Brothers v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed Cir. 1989). *See also*, MPEP § 2131.

Independent claim 2 recites a method for creating an electronic medication order. As defined in the Specification, orders are prescriptions for a patient that are directed to a pharmacy. *See* Specification, at page 20, lines 12-13 (¶ [0094]). As such, Villa-Real does not teach a method for creating an electronic medication order. Villa-Real discloses a handheld

medication-time-intake programmer and alarm system. Villa-Real does not teach creating prescriptions for a patient that are directed to a pharmacy. Rather, Villa-Real teaches a device to remind caretakers when to administer medications and what dosage to administer. Therefore, Villa-Real does not teach creation of an electronic medication order.

Independent claim 2 also recites displaying a list of medications and interactively receiving an input from a user selecting a medication from the list of available medications. Villa-Real does not teach displaying a list of medications, nor does Villa-Real teach receiving an input from a user selecting a medication from a list of available medications. Villa-Real merely teaches receiving an identification number for a medication, so as to distinguish it from other medications that the user has programmed into the device. *See*, Villa-Real, at col. 3, ll. 21-22. Therefore, Villa-Real does not teach displaying a list of available medications or interactively receiving an input from a user selecting a medication from the list of available medications.

Independent claim 2 also requires determining whether the selected medication is to be expertly dosed, and if so, expertly dosing the selected medication using a knowledge base. Villa-Real does not teach determining whether the selected medication is to be expertly dosed. Further, Villa-Real does not teach expertly dosing the selected medication using a knowledge base. Villa-Real merely teaches a handheld electronic device for reminding caretakers when to administer medications to particular patients and what dosage to administer. Villa-Real does not teach the ability to expertly dose a medication using a knowledge base of drug information.

Independent claim 2 further requires displaying to the user standard dosage recommendations for creating an electronic medication order if the selected medication is not to be expertly dosed. Villa-Real does not teach standard dosage recommendations. Further, claim 2 requires that the standard dosage recommendations include routes associated with the selected

medication. Villa-Real teaches no such associations between routes and selected medication. Further, Villa-Real does not disclose any ability to store any information about specific pharmaceutical agents, but rather merely stores a medication ID number input by the user, a patient ID number, and other dosage information that is input by the user. Therefore, Villa-Real does not teach displaying to the user standard dosage recommendations nor associations between routes and selected medications.

As Villa-Real does not teach each and every element of independent claim 2, Applicants respectfully request withdrawal of the 102 rejection with regard to claim 2. And, as claims 4 and 6 depend from claim 2, Applicants also respectfully request withdrawal of the 102 rejections with regard to those claims, as well.

Independent claim 7 recites a system for creating an electronic medication order for a patient. Villa-Real does not teach a system for creating an electronic medication order. As discussed above, an electronic medication order is directed to a pharmacy. Villa-Real does not teach the ability of the handheld device to create electronic medication orders directed to a pharmacy. Rather, Villa-Real merely teaches receiving information from a user for purposes of reminding a caretaker when to administer medications to patients and what dosage to give the patient. Therefore, Villa-Real does not teach a system for creating an electronic medication order.

Independent claim 7 further recites a first displaying component for displaying a list of available medications and a second receiving component for receiving an input from a user selecting a medication from the list of available medications. Villa-Real does not teach displaying a list of medications, nor does Villa-Real teach receiving an input from a user selecting a medication from a list of available medications. Villa-Real merely teaches receiving

an identification number for a medication, so as to distinguish it from other medications that the user has programmed into the device. *See*, Villa-Real, at col. 3, ll. 21-22. Therefore, Villa-Real does not teach a displaying component for displaying a list of available medications or a receiving component for interactively receiving an input from a user selecting a medication from the list of available medications.

Independent claim 7 also recites a knowledge base for expertly dosing medications and a determining component for determining whether a selected medication is to be expertly dosed. Villa-Real does not teach a knowledge base for expertly dosing medications nor does Villa-Real teach a determining component for determining whether a selected medication is to be expertly dosed.

As Villa-Real does not teach each and every element of independent claim 7, Applicants respectfully request withdrawal of the 102 rejection with regard to claim 7.

Rejections under 35 U.S.C. § 103

Claims 3, 5, and 8-13 were rejected under 35 U.S.C. 103(a) as being unpatenable over Villa-Real, and further in view of Brimm. As Villa-Real and Brimm fail to teach or suggest all limitations of each of claims 3, 5, and 8-13, Applicants respectfully request withdrawal of the 103 rejections.

One of the elements required to establish a *prima facie* case of obviousness is that the references, as combined, must teach or suggest all of the claim limitations. *See* MPEP § 2143. Here, Villa-Real and Brimm do not teach or suggest all of the claim limitations of each of claims 3, 5, and 8-13.

Claims 3 and 5 depend from independent claim 2, which recites a method for creating an electronic medication order. As indicated, orders are prescriptions for a patient that

are directed to a pharmacy. *See* Specification, at page 20, lines 12-13 (¶ [0094]). Villa-Real does not teach or suggest a method for creating an electronic medication order. Villa-Real discloses a handheld medication-time-intake programmer and alarm system. Villa-Real does not teach or suggest creating prescriptions for a patient that are directed to a pharmacy. Rather, Villa-Real teaches a device to remind caretakers when to administer medications and what dosage to administer. Therefore, Villa-Real does not teach or suggest creation of an electronic medication order.

Independent claim 2, from which claims 3 and 5 depend, also recites displaying a list of medications and interactively receiving an input from a user selecting a medication from the list of available medications. Villa-Real does not teach or suggest displaying a list of medications, nor does Villa-Real teach or suggest receiving an input from a user selecting a medication from a list of available medications. Villa-Real merely teaches receiving an identification number for a medication, so as to distinguish it from other medications that the user has programmed into the device. *See*, Villa-Real, at col. 3, ll. 21-22. Therefore, Villa-Real does not teach or suggest displaying a list of available medications or interactively receiving an input from a user selecting a medication from the list of available medications.

Independent claim 2, from which claims 3 and 5 depend, also requires determining whether the selected medication is to be expertly dosed, and if so, expertly dosing the selected medication using a knowledge base. Villa-Real does not teach or suggest determining whether the selected medication is to be expertly dosed. Further, Villa-Real does not teach or suggest expertly dosing the selected medication using a knowledge base. Villa-Real merely teaches a handheld electronic device for reminding caretakers when to administer

medications to particular patients and what dosage to administer. Villa-Real does not teach or suggest the ability to expertly dose a medication using a knowledge base of drug information.

Independent claim 2, from which claims 3 and 5 depend, further requires displaying to the user standard dosage recommendations for creating an electronic medication order if the selected medication is not to be expertly dosed. Villa-Real does not teach or suggest standard dosage recommendations. Further, claim 2 requires that the standard dosage recommendations include routes associated with the selected medication. Villa-Real teaches no such associations between routes and selected medication. Further, Villa-Real does not disclose any ability to store any information about specific pharmaceutical agents, but rather merely stores a medication ID number input by the user, a patient ID number, and other dosage information that is input by the user. Therefore, Villa-Real does not teach or suggest displaying to the user standard dosage recommendations nor associations between routes and selected medications.

Further, dependent claim 3 recites interactively receiving an input from the user selecting when the selected medication should be administered, and whether a generic substitute is acceptable. Neither Villa-Real nor Brimm teach or suggest interactively receiving an input from the user of whether a generic substitute is acceptable. Brimm merely teaches displaying information about the medication, including the “generic name” for the medication. *See*, Brimm, at col. 10, ll. 25-26. For example, in FIG. 6 of Brimm, terms such as “Mylanta” or “Valium” are displayed as generic names for drugs, rather than displaying their formal chemical names. This is different than receiving an input from a user indicating whether a generic drug can be substituted for a brand name pharmaceutical. The purpose in indicating whether such a substitute is acceptable is for cost-saving purposes, because generic drugs are often cheaper.

As Villa-Real and Brimm, either separately or in combination, do not teach or suggest all of the limitations of claim 3 or claim 5, Applicants respectfully request withdrawal of the 103 rejection as to claim 3 and 5.

Independent claims 8, 10, and 12 recite methods for creating an electronic medication order. Again, orders are prescriptions for a patient that are directed to a pharmacy. *See* Specification, at page 20, lines 12-13 (¶ [0094]). Villa-Real does not teach or suggest a method for creating an electronic medication order. Villa-Real discloses a handheld medication-time-intake programmer and alarm system. Villa-Real does not teach or suggest creating prescriptions for a patient that are directed to a pharmacy. Rather, Villa-Real teaches a device to remind caretakers when to administer medications and what dosage to administer. Therefore, Villa-Real does not teach or suggest creation of an electronic medication order.

Further, independent claims 8, 10, and 12 recite a step for determining a plurality of routes associated with a medication selected by a user. Neither Villa-Real nor Brimm teaches or suggests a step for determining a plurality of routes associated with a medication selected by a user. Claim 8 also recites a step for determining a plurality of dose forms associated with a selected medication and selected route. Neither Villa-Real nor Brimm teaches or suggests a step for determining a plurality of dose forms associated with a selected medication and selected route. Villa-Real and Brimm teach or suggest no such associations. Claim 10 also recites a step for determining a plurality of dose amounts associated with a selected medication and selected route. Neither Villa-Real nor Brimm teaches or suggests a step for determining a plurality of dose amounts associated with a selected medication and selected route. Villa-Real and Brimm teach or suggest no such associations. Claim 12 also recites a step for determining a plurality of frequencies associated with a selected medication and selected route. Neither Villa-Real nor

Brimm teaches or suggests a step for determining a plurality of frequencies associated with a selected medication and selected route. Villa-Real and Brimm teach or suggest no such associations.

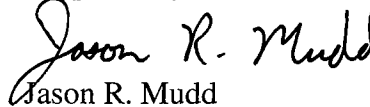
As Villa-Real and Brimm, separately or in combination, fail to teach or suggest all of the limitations of claims 8, 10, and 12, Applicants respectfully request withdrawal of the 103 rejections as to claims 8, 10, and 12. Further, Villa-Real and Brimm fail to teach or suggest all of the limitations of claims 9, 11, and 13, by virtue of their dependency from claims 8, 10, and 12. As such, Applicants further respectfully request withdrawal of the 103 rejections as to claims 9, 11, and 13, as well.

CONCLUSION

For at least the reasons stated above, claims 2-13 are in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of claims 2-13. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned by telephone prior to issuing a subsequent action.

No other fee, except for that required for the extension of time, is believed due in connection with this Amendment, but the Commissioner is hereby authorized to charge any additional amount required or to credit any overpayment to Deposit Account No. 19-2112.

Respectfully submitted,


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